

## RESEARCH INVOLVING PRISONERS AS SUBJECTS

**Project Code:** \_\_\_\_\_

**Project Title:** \_\_\_\_\_

### 45 CFR, Part 46, Subpart C – Additional Protections for Prisoners

**Check each requirement that has been met:**

☐ **§46.304 Composition of IRB's where prisoners are involved.**

At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

**§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.**

In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

☐ (1) the research under review represents one of the categories of research permissible under 46.306(a)(2);

☐ (2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

☐ (3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

☐ (4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

☐ (5) the information is presented in language which is understandable to the subject population;

☐ (6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and

each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

☐ (7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

**§46.306 Permitted research involving prisoners.**

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

☐ (1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under 46.305 of this subpart (for research funded by DHHS); and

**Check which section applies to this research:**

(2) in the judgment of the Secretary the proposed research involves solely the following:

☐ (A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

☐ (B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

☐ (C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

☐ (D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.